WAXMAN REMARKS: FDA/PA SELF-CARE SYMPOSIUM

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COPE: Our next speaker is far more than the chairman of the House Health Subcommittee. He's one of the most effective legislators ever to grace Capitol Hill. He's tough, but he's fair. He's open minded. He listens well, and he produces.
To mention just a few of his recent enactments, the Waxman-Hatch Price Competition and Patent Reform Act; the Orphan Drug Act; no fault compensation for children harmed by the use of vaccines; the Drug Export Bill, and the list could go on and on.

He's known in this city and increasingly around the country as "Mr. Health." So we're delighted to have him with us.

Just one other thing. He's a man I've known for some time. I admire and respect him I'm delighted he's here. Our keynoter of the afternoon, Congressman Henry A. Waxman.

Rep. Henry A. Waxman (D-Calif.)
Chairman, Health Subcommittee
U.S. House of Representatives

I'm delighted to be with you and to share a few observations about matters of concern to you and some of the legislation pending before us.

As Chairman of the Subcommittee on Health and the Environment, I get many invitations to speak. After nine years on the job, I still marvel at the very broad jurisdiction of our subcommittee. We have authority over Medicare and Medicaid; public health programs, including the National Institutes of Health, biomedical research. We have the FDA -- food, drug and medical device regulation; and environmental protection through the Clean Air and Safe Drinking Water Acts. What unites this array of divergent issues is our responsibility for promoting and maintaining the public health.

We deal with controversial issues all the time, but one area where experts and members of Congress have a complete consensus, over which there is really no controversy, is that whether faced with federal budget deficits or surpluses, we cannot afford to treat diseases that we can prevent.

Self Care

In the face of the double curse of persistent federal deficits and rising costs for health care, our ability to address serious health care problems

is severely curtailed. In this climate, it is clear that we must find new ways to prevent diseases and less expensive ways to treat illness.

Years ago our mothers told us that an ounce of prevention is worth a pound of cure. Good advice. There's wisdom to be found in old adages. Updated to 1988, and particularly given the interests of those of you here today, it could be said that pennies spent on self-care are worth dollars spent on health care.

There is a new generation of Americans today who are following this advice. For them good health is a driving, motivational force. They've made health clubs profitable businesses. They have put salad bars in fast food restaurants. They've elevated jogging to the level of a national passion. There is enormous public interest in personal fitness and diet. This trend is encouraging. It's not a fad. It is a permanent change in our American life style.

These Americans seek a life with minimal reliance upon expensive and sophisticated medical care services.

As a member of Congress concerned with public health, I see self-care in this broader context. Certainly it includes self-medication. But the essence of self-care -- from a public health perspective -- is individuals taking a wide variety of personal actions that promote and maintain their health.

Practicing self-care means going for necessary preventive health services such as prenatal care, periodic physicals, regular checkups at the dentist. It also means healthy life-styles, such as adequate exercise, not smoking, not drinking excessively, eating a healthy diet and wearing a seat belt when you drive your car.

We know these self-care activities pay off. Obesity can be prevented or controlled. Cardiovascular disease can be reduced through exercise and diet. Quitting or never smoking will dramatically reduce personal health risks. Diets rich in fiber and low in fat may reduce an individual's risk of cancer.

Good advice. If followed, we can have a stronger, healthier population. It is certainly good news to a federal budget beset by rising health care costs.

Call it self-care or call it healthy life-styles. It's an important national objective. But -- and this is an important "but" -- many of the activities we describe as self-care are heavily dependent upon

successfully communicating to the public the latest thinking of public health and medical experts.

The labeling, the advertisements, the public health messages are especially important in the areas of diet and self-medication. Science-based information is the foundation upon which decisions about diet and over-the-counter drugs are made. The public must be advised as to the foods that comprise a nutritious diet and how to effectively use over-the-counter medications. Information must be accurate and truthful. As important, it must be presented in a clear, concise fashion. Increasingly this health conscious generation is demanding information that in an earlier time was in the domain of scientists, doctors and nutritionists.

In classic economic theory, information is the self-correcting feature of the marketplace. Information encourages everyone to use resources efficiently.

The regulation of the fair use of information -- descriptions, claims, warnings or advertising -- is routinely accepted as part of the stock market and bond sales. It is advocated by the most respectable of conservatives. It is the foundation of financial markets.

But nutrition and over-the-counter drugs are different markets and even more dependent on information.

Nutrition products and over-the-counter drugs are not like other products. If cars or telephones or even bonds don't live up to manufacturers' claims, such failings are easy to discover and act on. If these goods have particular disadvantages, they can be seen or found.

But with foods or drugs, this information market is more difficult. Success is not obvious immediately, nor is failure, and the wrong guess can have severe consequences.

Consumers cannot separate foods that prevent cancer from foods that do nothing. Consumers have no independent way to determine the best medicines for their illnesses.

It is clear to me that the question is not whether to inform or regulate, but how it can best be done. In a society that is sometimes overwhelmed by information and technology, we must all decide how much government intervention is helpful.

O Government can make the decision entirely for the public, as all 50 states do when they require that children be immunized against polio.

O Government can regulate the public's decision as it does by making some drugs available only by prescription.

O Government can require disclosure of danger, as it does with cigarettes.

O Government can require proof of benefits, as it is supposed to do under both the FDA law for drugs and the FTC law for advertising.

O Or government can hope that private enterprise will somehow inform the public and that the public will recognize false claims.

I am sure that none of you will be surprised to know that I believe that the federal government has greater responsibility than merely to hope for the best.

I know that this group is concerned with distinguishing true benefits from good guesses. No one benefits from misinformation.

Self-Medication

Nowhere is the need for information greater than when consumers act as their own doctors or nurses.

Consumers like the opportunity to decide on the medications they take for minor ailments. They like being in control of minor health care decisions. As a result, there's a $9 billion market for over-the-counter drugs. That makes you important from the health and economic standpoint.

Decisions about medicines for skin rashes or stomach aches or chest colds are not trivial. They require a substantial amount of information and a safe and effective drug product.

That is what the law requires, and I know that is what you endeavor to provide for consumers.

The over-the-counter drug industry gets little attention from Congress, although I would guess that many of you think that's just fine. On some matters you also do not get as much attention from FDA as you need. That is bad.

Over-the-Counter Drug Review

The Over-the-Counter Drug Review is a perfect example of FDA giving you too little time.

Consumers generally are quite confident in over-the-counter medicines. I assume it stems from their experience and also from their belief that government would not let a drug be sold if there were any problems. But after 15 years, FDA still has a long way to go in completing the Review, and you have many important products that lack the FDA stamp of approval as effective.

You risk the loss of consumer confidence as the Review drags on. Consumers risk wasting millions of dollars on ineffective products and forgoing effective relief through other proven medicines.

I am painfully aware of the limited resources at FDA. The FDA's OTC Review staff needs more people, but so do many other important functions at FDA. I sympathize with Commissioner Young's dilemma. The administration and the Congress have not given FDA the additional staff that are needed. Under these adverse circumstances, I strongly urge you not to be passive. It is consumer confidence in your products that is at stake. It is in your interest to do everything you can to assist the FDA and even to push the FDA to complete the OTC review promptly.

Switching Rx to OTC

Another area where I know you would like to see greater FDA attention is in switching prescription drugs to over-the-counter status. As with so many FDA decisions, this one involves pros and cons.

Switching drugs from prescription controls recognizes the public's desire to make their important health care decisions. It gives them more effective tools to treat themselves. As more powerful prescription drugs are suggested for OTC status, though, we must also recognize that more and better information is necessary.

Doctors go through years of training in diagnosis and treatment for a reason. Consumers must fully understand the drugs they take and be sufficiently respectful of their risks. Consumers must never be enticed by subtle advertising to take drugs for untested or unproven indications.

Switching prescription drugs to OTC status requires considerable medical and scientific judgment. It also can produce enormous economic gains for industry. I expect that FDA's decisions will be the result of scientific scrutiny only. I trust FDA to

resist the inevitable political pressure from others with a vested interest or an ideological bent to market powerful drugs directly to the consumer.

Advertising ~~and~~ in the New Era

Selling medicines directly to the public carries a heavy burden. You are legally and morally obligated to label and advertise truthfully, completely and accurately.

The significance of your communications with consumers and the scrutiny they currently receive, will only increase as your industry enters a new era.

Our biomedical research establishment is constantly producing dazzling new information. Some of that, like the recent study of aspirin and heart attacks, directly affects the over-the-counter industry. In addition, you expect numerous important prescription drugs to be switched to over-the-counter status.

With each of these OTC "breakthroughs," consumers will have direct access to drugs which have far greater health consequences. For example, the recent heart study is not a recommendation for all men and women to begin a daily regimen of aspirin,

1but you would not know that from the recent surge in aspirin-heart disease related advertising. Nowhere is the public warned of the increased risk of stroke.

Such ads fail to fully and fairly inform the public who should not take aspirin. They are disservice to consumers and a public health hazard. ~~[STRONG STATEMENT -- TOO STRONG?]~~

These recent ads raise many of the same questions as does television advertising of prescription drugs. I strongly oppose consumer-directed prescription drug ads because their safe and effective use requires professional and medical judgment which consumers do not possess.

Consumers lack the necessary expertise to know when a prescription drug should be used. The advertisement then serves no educational purpose. Its sole function is to increase consumer pressure on physicians.

The same rationale is applicable to any over-the-counter medicine that can cause significant harm if taken by the wrong people or for the wrong use.

As you develop new advertising strategies and as you consider your labeling and other promotional material, you have the opportunity to advance the important societal goal of self-care. With proper restraint, your business interests can coincide with the public's interest.

That is where I hope the over-the-country drug industry will always be.

Product Liability

There's one other area that I thought would be of interest to you -- product liability. I have been supportive of efforts to provide this complex area with the careful scrutiny and thorough consideration it deserves.

In the case of a bill currently under consideration, I am working closely with several groups, including The Proprietary Association, and with other members to attempt to improve this bill and offer consumers who are killed and injured by defective products a fair chance to be compensated for their injuries. I have been supportive of efforts to try to achieve a uniform product liability law. I think there's a real important need for it. Businesses sell their products across state lines. They need to have some sense of what the rules will be from one place to another, and trying to operate with 50 separate rules often makes the situation intolerable.

But what we need to do is to make this bill a more balanced one that will, in fact, accomplish its two stated objectives: bringing about uniformity and bringing about some stabilization of the insurance market so that insurance will be available to manufacturers at a reasonable price.

Before I finish I would like to touch on the part of the proposed product liability legislation that I know is of major concern to you -- the "government standards" defense.

I understand fully the argument that a manufacturer whose product has met a strict government standard should not be subject to punitive damages for conduct within the scope of the Food and Drug Administration's review process. That is not necessarily a position that I would press for myself, but I do understand what you are looking for.

If a company goes to the FDA, goes through all of the review processes at FDA, gets an approval by the FDA, and acts in good faith, it shouldn't be subjected to a lawsuit for punitive damages when it has done all that it can be reasonably expected to do. In fact, that may be sufficient not just to eliminate punitive damages, but not to subject it to compensatory damages either.

What I think we must keep in mind is that any provision that gives a government standards defense should not apply where the manufacturer engaged in intentional and wrongful conduct that is not addressed by a government standard.

Such situations inevitably arise because the drug and device approval process cannot possibly discover all the problems that may arise with a new drug or new device. Once a company knows that its drug or device may harm people in a way that is unexpected, it should not be immune from punitive damages if its conduct is wrongful.

I am concerned that we not create an incentive for manufacturers to adopt a know-nothing, do-nothing policy about the side effects of their drugs and devices once they are on the market. This is because all they would have to do is follow FDA

regulations regarding reporting and relabeling and nothing more. In many cases where serious and unexpected adverse reactions occur, much more must be done to protect the public.

The important questions in determining whether there should be a bar to punitive damages are: (1) Whether the company acted wrongfully once it knew that consumers were likely to be hurt by the drug; and (2) whether the company acted, or did not act, at the direction or request of the FDA.

I intend to offer an amendment that would preclude punitive damages for a drug, including an over-the-counter drug that has an NDA or a Final Monograph, or device that was approved for safety and efficacy by the FDA, unless the manufacturer:

-- Intentionally and wrongfully withheld or misrepresented information required for approval or information on adverse reactions required to be submitted after approval;

-- Engaged in other intentional and wrongful conduct, taken after the drug was approved, that the manufacturer knew would be likely to result in harm

to an individual, unless the conduct resulted from a direction of the FDA;

-- Undertook illegal conduct relating to the safety or efficacy of a drug under any state law (such as a state law governing the approval or the labeling of a drug).

Also, the immunity provided by my amendment would extend to compliance with tamper-resistant packaging requirements.

Predictions about the ultimate fate of product liability legislation require a crystal ball better than mine. All I can tell you is that it will be controversial and hard-fought.

We've been working with your representatives here in Washington on how to craft that as it relates to the over-the-counter drugs because not all over-the-counter drugs go through FDA in the same way that prescription drugs do when they get their FDA final approval.

These are some of the issues before us. I consider myself a friend and supporter of your industry. We are, I think, trying to do the same thing: help

people make decisions for themselves; try to keep people well; try to avoid the use of the health care system unless it's necessary, and in doing that, we save money and we save lives and we help people.

Thank you very much for inviting me.

MFS/acd

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